What is Claimed Is:

1. A method of treating a bacterial infection in a human in need thereof, which method comprises administering to said human a dosage of a therapeutically effective amount of amoxicillin and potassium clavulanate, such that the amount of amoxicillin is in the range of 1900 to 2600 mg and the amount of potassium clavulanate is such that the weight ratio of amoxicillin to potassium clavulanate is from about 2:1 to 20:1, at a dosage regimen interval of about 12 hours.

2. The method according to claim 1 in which the weight ratio of amoxicillin to potassium clavulanate is from about 14:1 to 20:1.

3. The method according to claim 1 in which the dosage regimen provides a mean plasma concentration of amoxicillin of 4 μg/mL for at least 4.4 hours and a mean maximum plasma concentration (C_{max}) of amoxicillin of at least 12 μg/mL.

4. The method according to claim 3 in which the dosage regimen provides a mean plasma concentration of amoxicillin of 4 μg/mL for at least 4.8 hours and a mean maximum plasma concentration (C_{max}) of amoxicillin of at least 16 μg/mL.

5. The method according to claim 1 in which the dosage regimen provides a mean plasma concentration of amoxicillin of 8 μg/mL for at least 4.4 hours.

6. The method according to claim 1 in which the dosage is delivered from an immediate release formulation.

7. The method according to claim 6 in which the dosage is provided as a single tablet, or as a number of smaller tablets, some of which may be the same and some of which may comprise amoxicillin only and no potassium clavulanate.

8. The method according to claim 7 in which the dosage is 2000/125, 2250/125 or 2500/125 mg of amoxicillin and potassium clavulanate, respectively.

9. The method according to claim 1 in which the dosage is delivered from a modified release formulation.

10. The method according to claim 9 in which the dosage is provided as a number of tablets, some of which may be the same and some of which may comprise amoxicillin only and no potassium clavulanate.

11. The method according to claim 9 in which the dosage is 2000/125, 2250/125 or 2500/125 mg of amoxicillin and potassium clavulanate.

12. The method according to claim 1 in which the infection is caused by the organism *S. pneumoniae* (including Drug Resistant and Penicillin Resistant *S pneumoniae*), *H. influenzae* or *M. catarrhalis*.

13. A method of treating a bacterial infection in a human in need thereof, which method comprises administering to said human a dosage of a therapeutically effective amount of amoxicillin and potassium clavulanate such that the amount of amoxicillin is in the range 1400 to 1900 mg, and an amount of potassium clavulanate such that the weight ratio of amoxicillin to potassium clavulanate is from 2:1 to 14:1, at a dosage regimen interval of about 12 hours, such that the regimen provides a mean plasma concentration of amoxicillin of 4 µg/mL for at least 4.4 h, and a mean maximum plasma concentration (Cmax) of amoxicillin of at least 12 µg/mL.

14. The method according to in claim 13 in which the weight ratio of amoxicillin to potassium clavulanate is from 12:1 to 14:1.

15. The method according to claim 13 in which the dosage regimen provides a mean plasma concentration of amoxicillin of 4 µg/ml for at least 4.8 hours and a mean maximum plasma concentration (Cmax) of amoxicillin of at least 16 µg/ml.

16. The method according to claim 13 in which the dosage is delivered from a modified release formulation.

17. The method according to claim 13 in which the dosage is 1500/125 or 1750/125 mg of amoxicillin and potassium clavulanate.

18. The method according to claim 13 in which the infection is caused by the organism *S. pneumoniae* (including Drug Resistant and Penicillin Resistant *S pneumoniae*), *H. influenzae* or *M. catarrhalis*.

19. An immediate release pharmaceutical formulation comprising from 950 to 1300 or 1900 to 2600 mg of amoxicillin and an amount of potassium clavulanate such that the weight ratio of amoxicillin to potassium clavulanate is from 14:1 to 20:1, in combination with a pharmaceutically acceptable carrier or excipient.

20. The immediate release pharmaceutical tablet formulation according to claim 19 comprising 1000 mg ±5% amoxicillin and 62.5 mg ±5% potassium clavulanate, in a nominal ratio of about 16:1, in combination with a pharmaceutically acceptable carrier or excipient.

21. The immediate release pharmaceutical formulation according to claim 19 in the form of a single dose sachet comprising 2000, 2250 or 2500 mg ±5% amoxicillin and 125 mg ±5% potassium clavulanate, in a nominal ratio of about 16:1, 18:1 or 20:1, respectively, or the corresponding half quantities thereof, in combination with a pharmaceutically acceptable carrier or excipient.

22. The immediate release formulation according to claim 19 in the form of a dispersible tablet, chewable tablet, effervescent dispersible or effervescent chewable tablet comprising 2000, 2250, or 2500 mg amoxicillin and 125 mg ±5% potassium clavulanate, in a nominal ratio of about 16:1, 18:1 or 20:1, respectively, or the corresponding half quantities thereof, in combination with a dispersible, or chewable base and, if effervescent, an effervescent coupling agent, and a pharmaceutically acceptable or carrier or excipient.

23. A modified release pharmaceutical formulation comprising amoxicillin and potassium clavulanate in a (w/w) ratio from about 2:1 to 20:1, comprising an immediate release phase and a slow release phase; the immediate release phase comprising all the potassium clavulanate and a first part of amoxicillin, with a pharmaceutically acceptable carrier or excipient; and the slow release phase comprising a second part of amoxicillin formulated with a release modifying pharmaceutically acceptable excipient .

24. The modified release formulation according to claim 23 in which the ratio of amoxicillin and potassium clavulanate is 14:1 to 16:1.

25. The modified release formulation according to claim 23 which has a biphasic profile with respect to amoxicillin.

26. The modified release formulation according to claim 23 which has an AUC value which is at least 80% of that of the corresponding dosage of amoxicillin taken as a conventional (immediate release) tablet(s), over the same dosage period.

27. The modified release formulation according claim 23 in which the ratio of amoxicillin in the immediate and slow release phases is from 3:1 to 1:3.

28. The modified release formulation according claim 23 comprising a unit dosage form in the range 700 to 1300 mg amoxicillin or 1400 to 2600 mg and a corresponding amount of potassium clavulanate.

29. The modified release formulation according to claim 28 in which the unit dosage is: 1000, 875 or 750 mg ±5% amoxicillin and 62.5 mg ±5% potassium clavulanate; or 2000, 1750 or 1500 mg ±5% amoxicillin and 125 mg ±5% potassium clavulanate; in a nominal ratio of about 16:1, 14:1 or 12:1, respectively, in combination with a pharmaceutically acceptable excipient or carrier.

30. The modified release formulation according to claim 29 in the form of a tablet.

31. The modified release formulation according to claim 30 comprising 1000 mg ±5% amoxicillin and 62.5 mg ±5% potassium clavulanate, in a nominal ratio of about 16:1; and in which the immediate release phase comprises about 563 mg ±5% amoxicillin and about 62.5 mg ±5% of potassium clavulanate, and the slow release phase comprises about 438 mg ±5% of amoxicillin.

32. The modified release formulation according to claim 23 in which the amoxicillin of the slow release phase consists essentially of crystallised sodium amoxicillin.

33. The modified release formulation according to claim 23 which is a layered tablet and in which the immediate and slow release phases are provided for as separate layers of the layered tablet.

34. The layered tablet according to claim 33 in which the slow release layer further comprises a release retarding excipient which is selected from a pH sensitive polymer, a release-retarding polymer which has a high degree of swelling in contact with water or aqueous media, a polymeric material which forms a gel on contact with water or aqueous media, a polymeric material which has both swelling and gelling characteristics in contact with water or aqueous media, or mixtures thereof.

35. The layered tablet according to claim 34 in which the release retarding gellable polymer is selected from methylcellulose, carboxymethylcellulose, low-molecular weight hydroxypropylmethylcellulose, low-molecular weight polyvinylalcohols, polyoxyethyleneglycols, non-cross linked polyvinylpyrrolidone, or xanthan gum.

36. The layered tablet according to claim 34 in which the release retarding excipient is xanthan gum.

37. The layered tablet according to claim 36 in which the xanthan gum is present in from 4 to 25% by weight of the layer.

38. The layered tablet according to claim 33 in which the slow release layer comprises from about 70 to 80% of amoxicillin, from about 4 to 25% of xanthan gum, from about 10 to 20% of fillers and/or compression agents, and a conventional quantity of a lubricant.

39. The layered tablet according to claim 33 in which the slow release phase comprises sodium amoxicillin and in which the slow release layer comprises a pharmaceutically acceptable organic acid present in a molar ratio of from 100:1 to 1:10 (amoxicillin salt to organic acid).

40. The layered tablet according to claim 39 in which the pharmaceutically acceptable acid is citric acid present in a molar ratio of about 50:1 to 1:2.

41. The layered tablet according to claim 40 further comprising a release retarding gellable polymer.

42. The layered tablet according to claim 41 in which the release retarding gellable polymer is xanthan gum.

43. The layered tablet according to claim 42 in which xanthan gum is present in from 0.5 to 8% by weight of the slow release layer.

44. The layered tablet according to claim 33 comprising in total about 700 to 1250 mg amoxicillin and a pro rata amount of potassium clavulanate, in a nominal ratio of about 16:1, 14:1 or 12:1, respectively, in combination with a pharmaceutically acceptable excipient or carrier.

45. The layered tablet according to claim 39 which comprises in the immediate release layer about 1000 mg ±5% of amoxicillin and 62.5 mg ±5% of potassium clavulanate, and in the slow release layer about 438 mg ±5% of crystallised sodium amoxicillin, about 78 mg ±10% of citric acid and about 2% by weight of xanthan gum.

46. The modified release formulation according to claim 23 in which the immediate release phase is formed from immediate release granules comprising amoxicillin and potassium clavulanate; or immediate release granules comprising amoxicillin and potassium clavulanate admixed with a further immediate release granule comprising amoxicillin and the slow release phase is formed from slow release granules comprising amoxicillin.

47. The modified release formulation according to claim 46 which is formulated as a unit dose sachet, capsule, monolith tablet, dispersible tablet, chewable tablet, effervescent chewable tablet, or a effervescent dispersible tablet.

48. A pharmaceutical formulation comprising 1000 mg ±5% amoxicillin and 62.5 mg ±5% potassium clavulanic acid, in a nominal ratio of about 16:1, in combination with a pharmaceutically acceptable excipient or carrier.

49. The pharmaceutical formulation according to claim 48 in which the amoxicillin is present as a mixture of amoxicillin trihydrate and sodium amoxicillin in a ratio of 3:1 to 1:3.

50. A pharmaceutical formulation comprising amoxicillin and potassium clavulanate in a ratio of from 1:1 to 30:1 in which amoxicillin is provided as a mixture of amoxicillin trihydrate and sodium amoxicillin in a ratio of from 3:1 to 1:3.

51. The pharmaceutical formulation according to claim 50 in which the ratio of amoxicillin trihydrate and sodium amoxicillin is from 3:2 to 2:3.

52. A pharmaceutical formulation comprising a pharmaceutically acceptable soluble salt of amoxicillin in a slow release phase which further comprises a release retarding excipient which is a pharmaceutically acceptable organic acid present in a molar ratio of from 100:1 to 1:10 (amoxicillin salt to organic acid).

53. The pharmaceutical formulation according to claim 52 in which the molar ratio is 50:1 to 1:5.

54. The pharmaceutical formulation according to claim 52 in which the organic acid is citric acid.

55. The pharmaceutical formulation according to claim 52 in which the soluble salt of amoxicillin is sodium amoxicillin.

56. A kit comprising an immediate release formulation comprising amoxicillin and potassium clavulanate, optionally with a conventional (immediate release) formulation comprising amoxicillin and a slow release formulation comprising amoxicillin (and no potassium clavulanate).

57. A slow release pharmaceutical formulation comprising amoxicillin (as the sole active ingredient) formulated with a release retarding excipient which causes a slow release of the amoxicillin from the formulation, and excluding tablets which comprise from 400 to 500 mg amoxicillin trihydrate or a mixture comprising at least 70% amoxicillin trihydrate and up to 30% sodium amoxicillin and hydroxypropylmethylcellulose.

58. The pharmaceutical formulation according to claim 57 which comprises 100 to 1250 mg amoxicillin.

59. A pharmaceutical formulation according to claim 57 in which the release retarding excipient is xanthan gum.

60. A pharmaceutical formulation according to claim 59 in which the xanthan gum is pharmaceutical grade xanthan gum, 200 mesh.

61. A pharmaceutical formulation according to claim 59 in which the xanthan gum is present in from about 0.5 to 25% by weight.

62. Compacted granules for use in a pharmaceutical formulation comprising amoxicillin a diluent or compression aid, and an organic acid (if amoxicillin is present as a soluble salt thereof), or release retarding polymer, or a mixture thereof.

63. Compacted granules for use in a pharmaceutical formulation comprising sodium amoxicillin, microcrystalline cellulose, and an organic acid or a release retarding polymer or a mixture thereof.

64. A process for preparing compacted granules according to 63 which process comprises the steps of blending together sodium amoxicillin, microcrystalline cellulose, and organic acid or release retarding polymer or mixture thereof, compacting the blend and then milling.

65. The pharmaceutical formulation according to claim 46 comprising slow release compacted granules comprising amoxicillin, a diluent/compression aid, and an organic acid (if amoxicillin is present as a soluble salt thereof) or a release retarding polymer or a mixture thereof, and immediate release compacted granules comprising amoxicillin and potassium clavulanate or immediate release compacted granules comprising amoxicillin and potassium clavulanate, and further immediate release compacted granules comprising amoxicillin.

66. A formulation according to claim 23 having an AUC, C_{max}, and t_{max} substantially according to Figure 5 (formulation VI or VII).

67. A formulation which is bioequivalent to the formulation of claim 66.

68. A method of treating bacterial infections in humans which comprises orally administering thereto a therapeutically effective amount of amoxicillin and potassium clavulanate such that the amount of amoxicillin is in the range 1250 to 1750 mg, and the amount of potassium clavulanate is such that the weight ratio of amoxicillin to clavulanate is from 2:1 to 20:1, at intervals of about 8 h, in which the dosage is delivered from a modified release formulation.

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